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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,703	10/07/2003	Joseph Morelli	110088.454	2633

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/680,703	**Applicant(s)** MORELLI ET AL.	
	Examiner Donna Jagoe	**Art Unit** 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-28 and 31-48* is/are pending in the application.

4a) Of the above claim(s) *20-22 and 38-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 18, 19, 23-28 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed November 19, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-16, 18-28 and 31-48 are pending in this application.

Claims 20-22 and 38-48 are withdrawn.

Claims 1-16, 18, 19, 23-28 and 31-37 are rejected.

Terminal Disclaimer

The terminal disclaimer filed on November 9, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,916,493 and 6,524,624 has been reviewed and is accepted. The terminal disclaimer has been recorded.

New Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 10-13, 18, 19, 26-28, 31-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roozdar U.S. Patent No. 5,380,518 A and Morelli et al. U.S. Patent No. 6,524,624 B1.

Roozdar teaches a two part disinfecting system comprising a first and second part to be mixed prior to use comprising a soluble chlorite salt in the first part (see abstract) such as sodium and potassium chlorite (column 3, lines 29-35; column 7, lines 35-41) and an acidic part comprising, *inter alia,* lactic acid, and sulfamic acid and mixtures thereof (column 7, lines 42-63; claim 2). The pKa of the acid is about 2.1 which is within the instantly claimed range of 2-5 (column 3, lines 46-49). The final pH of the disinfecting system when combined is below 5, and preferably less than about 1.8 (column 6, lines 33-35; column 10, lines 11-15). Roozdar discloses a 1:1 ratio of a combination of the two part formula in the form of a liquid (aqueous solution)(see example 5, column 13, lines 11-44). It is noted that sulfamic acid is present, but it is not disclosed as being a “nitrogenous stabilizer. Further, although not explicitly stated, sulfamic acid is a primary amine. “Products of identical chemical composition (i.e. sulfamic acid) can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. nitrogenous stabilization) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Regarding the Reduced Chlorite Demand Factor of 2 or greater, 3 or greater and 4 or greater, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Roozdar et al. does not teach an oxidizable colorant present in the first part, the second part or both the first and second parts.

Morelli et al. teach a two-part disinfecting system that when mixed, yields a disinfecting composition wherein oxidizable colorants are added (column 2, lines 20-25). It is further disclosed that color is desirable in the disinfecting composition because it allows the user to visually confirm that the disinfectant has been properly applied. The optional colorant is in the first part or the second part or both (see claim 1). It would have been made obvious to one of ordinary skill in art at the time it was made to employ a color in the two part disinfecting system of Roozdar motivated by the teaching of Morelli et al. that color is desirable to confirm the presence of the disinfectant agent.

Claims 1-6, 10-13, 31-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastore U.S. Patent No. 6,071,483 A. and Morelli et al. U.S. Patent No. 6,524,624 B1.

Pastore teaches a chlorine dioxide solution that is made with a two-chambered vessel (column 6, line 39 to column 7, line 15) with a chlorite such as sodium chlorite and potassium chlorite, with sodium chlorite being particularly preferred (column 4, lines 48-57). Disclosed is an organic acid such as lactic acid and inorganic acid such as sulfamic acid and mixtures thereof (column 4, line 61 to column 5, line 8). These agents are disclosed to be in aqueous solution (see examples 1-8). It is noted that sulfamic acid is present, but it is not disclosed as being a "nitrogenous stabilizer. Further, although not explicitly stated, sulfamic acid is a primary amine. "Products of identical chemical composition (i.e. sulfamic acid) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. nitrogenous stabilization) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Regarding the Reduced Chlorite Demand Factor of 2 or greater, 3 or greater and 4 or greater, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. It does not teach the oxidizable colorant, present in the first part, the second part or both the first and second parts.

Morelli et al. teach a two-part disinfecting system that when mixed, yields a disinfecting composition wherein oxidizable colorants are added (column 2, lines 20-25). It is further disclosed that color is desirable in the disinfecting composition because it allows the user to visually confirm that the disinfectant has been properly applied. The optional colorant is in the first part or the second part (see claim 1). It would have been made obvious to one of ordinary skill in art at the time it was made to employ a color in the two part disinfecting system of Pastore motivated by the teaching of Morelli et al. that color is desirable to confirm the presence of the disinfectant agent.

Claims 1-16, 18, 19, 23-28 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al. U.S. Patent No. 6,379,685 B1.

Richter et al. teach an admixture comprised of two cooperative parts, the first part of major or equal proportion having an aqueous mixture of an acid and the second part of equal or minor proportion of an alkali metal chlorite wherein they are mixed for an immediate application as soon as needed (column 7, line 64 to column 8, line 50). Preferred acids include organic and inorganic acids such as lactic acid, sulfonic acids and mixtures thereof (column 9, line 64 to column 10, line 6). Preferred chlorine release compounds are alkaline earth chlorinated derivatives, such as sodium chlorite (column 6, lines 21-29). It is noted that sulfamic acid is present, but it is not disclosed as being a "nitrogenous stabilizer. Further, although not explicitly stated, sulfamic acid is a primary amine. "Products of identical chemical composition (i.e. sulfamic acid) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. nitrogenous stabilization) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Regarding the Reduced Chlorite Demand Factor of 2 or greater, 3 or greater and 4 or greater, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Richter et al. disclose that a pH of greater than 5 is unacceptable because it reduces the effeciency of the composition and a pH of less than 1 is unacceptable because it can result in substantial irritation (column 9, lines 50-63; column 12, lines 61-63).

It does not teach that the acid portion has a pKa of 2-5. Regarding applicant's allegation that the pKa makes the composition different, the pKa of a compound is related to the pH of the solution when it is at equilibrium between its acid and base forms. In more depth, the pH is the negative logarithm of the hydrogen ion concentration in a solution (a reflection of the acidity of the solution - the more hydrogen ions, the more acidic the solution, and the lower the pH). Hence, if the pH is the same, and the acid/acid salt employed is the same, then the pKa would be the same. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

The optional addition of a chromophore, dye or pigment (oxidizible colorant) is disclosed (see column 9, lines 12-21; Examples III-V, and X-XIV). See, *inter alia*, example IV, column 20, wherein the pigment is in the second part (acidic portion). As noted above the two portions are mixed in equal parts (column 7, line 64 to column 8, line 60). A solid formulation is contemplated in column 8, line 21. Further thickening and film forming agents are disclosed throughout, such as column 11, line 16 to column 12, line 34.

Richter's preferred acids include organic and inorganic acids such as lactic acid, sulfonic acids and mixtures thereof (column 9, line 64 to column 10, line 6). Preferred chlorine release compounds are alkaline earth chlorinated derivatives, such as sodium chlorite (column 6, lines 21-29). The claimed concentration of the nitrogenous stabilizer (sulfamic acid) when the first and second parts are combined is 0.001% to about 20% by weight. Richter et al. does not teach a specific amount of “nitrogenous stabilizer”, however the presence of sulfamic acid is disclosed. Ranges of the amount of acidulant and/or antimicrobial are disclosed as from 1%-12 wt % (column 17, lines 55-60) which is encompassed the claimed amounts of from .001% to about 20%. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious. Regarding the amount of chlorite present when combined with the second part, the reference is silent in this aspect, but discloses the amounts of the acid/chlorite combined. These amounts partially overlap and encompass the claimed amount of 0.005% to about 3%. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious. Regarding the amount of acid present in the second part such that, when combined with the first part, it is present in a concentration of 0.1 % to about 10 % by weight, Richter et al. does not teach the combined percentage specifically however, the ranges of the amount of acidulant and/or antimicrobial are disclosed as from 1%-12 wt % (column 17, lines 55-60). This partially overlaps the claimed range. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious.

Response to Arguments

Regarding the rejection made over Richter et al. Applicant asserts that the prior art would not motivate one of ordinary skill in the art to select among such a list of elements to produce the claimed two-part disinfecting system In response to applicant's argument that that the prior art makes no distinction between acids which are nitrogenous stabilizers and acids which are not and oxidizable colorants and non-oxidizable colorants, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Regarding the oxidizable colorant, all colorants/dyes are oxidizable, such as the oxidation of dyes when exposed to UV light. Further, a reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., enhanced production of chlorine dioxide) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner directs Applicant's attention to *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Further*, Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied,* 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab,LLC*, 412 F.3d 1319, 1323, 75 USPQ2d

1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. “The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.”) Thus, the question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis. Consequently, this argument does not raise an issue of material fact.

Regarding the request to rejoin claims 20-22 and 38-48, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

March 7, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614